510(K) SUMMARY

NOV 2 8 2012

Trade Name: AZUR PURE Peripheral Coil System, Pushable 18 & 35

Generic Name: Vascular Embolization Coil

Classification: Class II, 21 CFR 870.3300

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California 92780 U.S.A.

Contact: Laraine Pangelina

Predicate Device: AZUR Peripheral HydroCoil Endovascular Embolization Coil System, Pushable 18 and 35 (K071939, K091882)

Device Description:

The AZUR PURE Peripheral Coil System, Pushable 18 & 35, consists of an implantable all-polymer coil housed in an introducer. A stainless steel stylet is used to deploy the coil from the introducer into a delivery catheter. The coil is delivered to the treatment site through the delivery catheter using a standard guidewire.

Indications for Use:

The AZUR PURE is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

Verification and Validation Test Summary:

Test	Result
Simulated Use	Met established criteria
Dimensional Characteristics	Met established criteria
Tensile Strength	Met established criteria
Advancement Force	Met established criteria
FTIR	Met established criteria
HydroStability	Met established criteria
MRI Compatibility	Met established criteria
Electrical Conductivity	Met established criteria
Packaging Validation	Met established criteria
Sterilization validation	Met established criteria
Shelf Life	Met established criteria
Biocompatibility	Met established criteria
Acute & Chronic Animal Testing	Met established criteria

Technological comparison, subject and predicate device:

	Predicate Devices (K071939, K091882	AZUR PURE, 510(k) Subject Device
Coil Shape	Helical	Same
Coil OD (mm)	AZUR 18: 2 - 10 AZUR 35: 3 - 16	AZUR 18: 3 - 10 AZUR 35: 4 - 15
Coil Length (cm)	AZUR 18: 2 - 14 AZUR 35: 4 - 14	AZUR 18: 2 - 20 AZUR 35: 4 - 14
Delivery Method	Coil housed in an introducer with proximal hub. Pushable delivery using guidewire.	Same
Hydrogel Implant Material	Hydrophilic copolymer	Same
Packaging Configuration	Placed in capped coil introducer, placed on packaging card, into pouch, into box, 5/box	Same

Summary of Substantial Equivalence:

The AZUR PURE Peripheral Coil System, Pushable 18 & 35 is substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 2 8 2012

Microvention, Inc.
% Laraine Pangelina
1311 Valencia Ave
Tustin, CA 92780 US

Re: K122543
Trade/Device Name: AZUR PURE peripheral coil system
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: November 2, 2012
Received: November 8, 2012

Dear Ms. Pangelina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122543

Device Name: AZUR PURE Peripheral Coil System, Pushable 18 & 35

Indications for Use: The AZUR PURE is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

Prescription Use _X_ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M Y Hilleher

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122543